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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Edward Harold Schad, Jr., Plaintiff, v. Janice K. Brewer, Governor of Arizona; Charles L. Ryan, Director, Arizona Department of Corrections; Ron Credio, Warden, Arizona Department of Corrections-Eyman; Lance Hetmer, Warden, Arizona Department of Corrections-Florence, Defendants.	Case No.2:13-cv-02001-ROS **Motion of Robert Glen Jones Jr. to Intervene Pursuant to Fed. R. Civ. P. 24(a) and (b)**

Pursuant to Rule 24(a) and (b) of the Federal Rules of Civil Procedure, Robert Glen Jones, through undersigned counsel, respectfully moves to intervene in the above-captioned proceeding under 42 U.S.C. § 1983. Counsel for Plaintiff, Edward Harold Schad, Jr., do not oppose the motion. Per email communications, Counsel for Defendants do not oppose intervention. Mr. Jones's motion is supported by the attached memorandum in support.

Appended to this Motion is Plaintiff's Complaint.

Respectfully submitted this 3rd day of October 2013.

Jon M. Sands
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s/ Dale A. Baich
Counsel for Plaintiff

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Edward Harold Schad, Jr., Plaintiff, v. Janice K. Brewer, Governor of Arizona, Scott Smith, Chief of Staff to Governor Brewer, Brian Livingston, Chairman and Executive Director. Arizona Board of Clemency, John Lasota, Member, Arizona Board of Executive Clemency, Ellen Kirschbaum, Member, Arizona Board of Executive Clemency, Donna Harris, Member, Arizona Board of Executive Clemency, Defendants.	Case No.2:13-cv-02001-ROS **Memorandum in Support of Motion of Robert Glen Jones Jr. to Intervene Pursuant to Fed. R. Civ. R. 24(a) and (b)**

On September 26, 2013, Plaintiff Edward Harold Schad, an Arizona death row prisoner with a scheduled execution date of October 9, 2013, filed a complaint for equitable, injunctive, and declaratory relief pursuant to 42 U.S.C. §§ 1983. Mr. Schad alleged, *inter alia*, that the Arizona Department of Corrections ("ADOC"), while acting under the color of state law, violated his First Amendment right of access to governmental proceedings in the execution context,

and his right to due process under the Fourteenth Amendment to the United States Constitution. *Schad v. Brewer*, 2:13-cv-02001-ROS, (District Court Docket Number ("Dkt.") 1.)

Proposed intervenor Robert Glen Jones is also an Arizona death row prisoner with a scheduled execution date of October 23, 2013. Because the factual and legal issues presented in Mr. Schad's § 1983 action apply with equal force to Mr. Jones, he now moves, pursuant to both Rule 24(a) and (b) of the Federal Rules of Civil Procedure, to intervene in that proceeding. Finally, Defendants do not oppose Plaintiff's motion.

Argument

A. Mr. Jones satisfies the requirements for intervention as of right under Fed. R. Civ. P. 24(a)(2).

Rule 24(a) of the Federal Rules of Civil Procedure provides in relevant part:

> (2) claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest.

Fed. R. Civ. P. 24(a).

Thus, to intervene as of right, Mr. Jones must demonstrate that (1) he has a significant protectable interest relating to the property or transaction that is the subject of the action; (2) the disposition of the action may, as a practical matter, impair or impede his ability to protect his interest; (3) the application is timely; and (4) the existing parties may not adequately represent the applicant's interest. *United States v. City of Los Angeles*, 288 F.3d 391, 397 (9th Cir. 2002) (quoting *Donnelly v. Glickman*, 159 F.3d 405, 409 (9th Cir. 1998)). *See also Day v. Apoliona*, 505 F.3d 963, 965 (9th Cir. 2007) (granting motion to intervene of State of Hawaii under Fed. R. Civ. P. 24(a)(2) because disposition of the action might impede the State's ability to protect its interests because, in part, the opinion of the court "may have a precedential impact regarding the availability of an enforceable

right of action under § 1983"). Mr. Jones satisfies each requirement to intervene as of right.

1. Mr. Jones has a significant protectable interest in the litigation.

"An applicant has a 'significant protectable interest' in an action if (1) [he] asserts an interest that is protected under some law, and (2) there is a 'relationship' between [his] legally protected interest and the plaintiff's claims." *Donnelly*, 159 F.3d at 409 (internal citation omitted). The relationship requirement is met "if the resolution of the plaintiff's claims actually will affect the applicant." *Id.* at 410. The "interest" test is not a clear-cut or bright-line rule, because "no specific legal or equitable interest need be established." *Greene v. United States*, 996 F.2d 973, 976 (9th Cir 1993) (internal citation omitted). Instead, the "interest" test directs courts to make a "practical, threshold inquiry." *Id.* It "is primarily a practical guide to disposing of lawsuits by involving as many apparently concerned persons as is compatible with efficiency and due process." *City of Los Angeles*, 288 F.3d at 398 (quoting *County of Fresno v. Andrus*, 622 F.2d 436, 438 (9th Cir. 1980)); *see also Sw. Ctr. for Biological Diversity v. Berg*, 268 F.3d 810, 818 (9th Cir. 2001) (internal citation omitted) ("In general, we construe Rule 24(a) liberally in favor of potential intervenors."); *Donnelly*, 159 F.3d at 409 (internal citation omitted) ("In determining whether intervention is appropriate, we are guided primarily by practical and equitable considerations. We generally interpret the requirements broadly in favor of intervention.").

Like Mr. Schad, Mr. Jones has a scheduled execution date. Mr. Jones requested certain information from ADC regarding the drugs it intends to use in his scheduled execution. ADC did not provide the requested information. Mr. Jones has the same First Amendment right of access to governmental proceedings in the execution context, and his right to due process under the Fourteenth Amendment to the United States Constitution, as Mr. Schad. There is a significant relationship between the allegations and claims in Mr. Schad's

Complaint and Mr. Jones's Complaint, and the resolution of Mr. Schad's claims will necessarily determine whether and how Mr. Jones's clemency hearing is conducted.

2. Disposition of the action may, as a practical matter, impair or impede Mr. Jones's ability to protect his interest.

The ultimate resolution of the issues presented in this litigation may impair and impede Mr. Jones's ability to protect his First and Fourteenth Amendmend rights. Establishing that disposition of an action may impair or impede an applicant's ability to protect his interest requires only a hypothetical showing: an applicant is not required to show "substantial impairment" of his interests or that "impairment will inevitably ensue from an unfavorable decision." *Purnell v. Akron*, 925 F.2d 941, 947 (6th Cir. 1991). Rather, as stated in Rule 24, he need only show that the disposition may harm his ability to protect his interests. For that reason, the *stare decisis* effect of a potentially adverse ruling is sufficient to show impairment. *See United States v. Oregon*, 839 F.2d 635, 638 (9th Cir. 1988). There can be little doubt that Defendants will invoke any potential adverse precedent established by Mr. Schad's litigation in any future litigation by Mr. Jones. Moreover, disposition of Mr. Schad's case will have a direct impact on Mr. Jones's ability to vindicate his First and Fourteenth Amendment rights as outlined in Claims 1 and 2 of his Complaint, as those claims are virtually identical to Claims 1 and 2 in Mr. Schad's complaint. *See* Exhibit A (Complaint).

3. This motion to intervene is timely.

Three criteria govern whether a motion to intervene is timely: "(1) the stage of the proceedings; (2) whether the parties would be prejudiced; and (3) the reason for any delay in moving to intervene." *Northwest Forest Res. Council v. Glickman*, 82 F.3d 825, 836-37 (9th Cir. 1996) (citing *United States v. Oregon*, 913 F.2d 576, 588 (9th Cir. 1990)). Mr. Jones has moved quickly to protect his rights. Mr. Schad's lawsuit was filed on October 2, 2013. Mr. Jones has moved

to intervene the next day. Defendants, have not yet filed a responsive pleading to the complaint. Therefore, the proposed intervention will not impair the process of the proceedings or impact the interests of the original parties. This motion is timely.

4. Plaintiff Schad may not adequately represent Mr. Jones's interests in this litigation.

The inadequate representation prong of the test requires only a minimal and hypothetical showing. To determine whether the existing parties adequately represent an applicant's interest, this Court must consider: "(1) whether the interest of a present party is such that it will undoubtedly make all the intervenor's arguments; (2) whether the present party is capable and willing to make such arguments; and (3) whether the would-be intervenor would offer any necessary elements to the proceedings that other parties would neglect." *City of Los Angeles*, 288 F.3d at 398 (quoting *Glickman*, 82 F.3d at 838). "The requirement of inadequate representation 'is satisfied if the applicant shows that representation of his interest [by existing parties] 'may be' inadequate.'" *Id.* (citing *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972)). There is only "a minimal showing needed to establish that the [plaintiff's] representation 'may' be inadequate." *City of Los Angeles*, 288 F.3d at 402.

Here, the nature of Mr. Jones's claims makes intervention necessary to protect his interests because Mr. Schad's litigation does not contemplate the independent schedule of Mr. Jones's case. Mr. Jones has a separate and distinct execution date. Further, although the factual and legal issues in Mr. Schad's § 1983 case apply with equal force to Mr. Jones.

Representing Mr. Jones's interests requires the ability to raise, present, and protect through litigation his own First Amendment right, as well as his right to due process. Moreover, Mr. Schad will be unable to protect Mr. Jones's interests if no court grants a stay of execution and he is executed. Without being a party to

the litigation, Mr. Jones will not have the ability to appeal the claims and fully litigate and vindicate his rights. *See City of Los Angeles*, 288 F.3d at 400 (intervenor-applicant would lack the ability to formally raise issues and arguments or appeal decision unless made party to the action). Thus, given Mr. Schad's imminent execution date, Mr. Schad's representation of Mr. Jones's interests, at the very least, "may be" inadequate

B. In the alternative, this Court should exercise its discretion to permit Mr. Jones to intervene in the litigation pursuant to Fed. R. Civ. P. 24(b)(1)(B).

Pursuant to Federal Rules of Civil Procedure 24(b), a court may permit an applicant to intervene when he "has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). "[A] court may grant permissive intervention where the applicant for intervention shows (1) independent grounds for jurisdiction; (2) the motion is timely; and (3) the applicant's claim or defense, and the main action, have a question of law or a question of fact in common." *City of Los Angeles*, 288 F.3d at 403 (quoting *Glickman*, 82 F.3d at 893).

Here, Mr. Jones is able to assert the same grounds for jurisdiction set forth by Mr. Schad in his complaint in this case. *See* Dkt. 1 at 4; Exhibit A (Complaint) at ¶¶ 14-16. For the reasons stated above, Mr. Jones's motion to intervene is timely. Moreover, Mr. Jones's claims share virtually identical questions of law and fact with Mr. Schad's claims. Finally, judicial economy suggests that these same claims, based on an almost same set of facts and the same legal theory, be resolved in one proceeding.

Accordingly, Mr. Jones respectfully requests that the Court exercise its discretion to permit him to intervene in this action pursuant to Fed. R. Civ. P. 24(b)(1)(B).

Respectfully submitted this 3rd day of October 2013.

Jon M. Sands
Federal Public Defender
Dale A. Baich
Robin C. Konrad

s/ Dale A. Baich
Counsel for Petitioner-Appellant

Certificate of Service

I hereby certify that on October 3, 2013 , I electronically filed the foregoing Motion of Robert Glen Jones Jr. to Intervene Pursuant to Fed. R. Civ. P. 24(a) and (b) with the Clerk's Office by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/ Chelsea L. Hanson
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Robert Glen Jones, Jr., Plaintiff, v. Janice K. Brewer, Governor of Arizona; Charles L. Ryan, Director, Arizona Department of Corrections; Ron Credio, Warden, Arizona Department of Corrections-Eyman; Lance Hetmer, Warden, Arizona Department of Corrections-Florence; Defendants.	Case No.2:13-cv-02001 COMPLAINT FOR EQUITABLE, INJUNCTIVE, AND DECLARATORY RELIEF [42 U.S.C § 1983] **Execution Scheduled October 23, 2013**

Nature of Action

1. This action is brought pursuant to 42 U.S.C. § 1983 for violations and threatened violations by the Arizona Department of Corrections ("ADC") of Plaintiff's First Amendment right of access to governmental proceedings in the execution context, and his right to due process under the Fourteenth Amendment to the United States Constitution.

2. This Complaint does not challenge Plaintiff's underlying capital conviction or sentence of death, nor does it allege that lethal injection as a form of execution is *per se* unconstitutional.

3. Plaintiff has reason to believe that ADC intends to execute him with pentobarbital that is expired.

4. Plaintiff alleges that Defendants' failure to provide him with proper notice regarding the pentobarbital ADC intends to use in his execution violates his First Amendment right of access to governmental proceedings in the execution context, and his due-process rights under the Fourteenth Amendment of the United States Constitution.

5. Plaintiff alleges that Defendants' lack of transparency regarding their supply of pentobarbital—demonstrated by their refusal to provide information to him—violates his First Amendment right of access to governmental proceedings in the execution context, and by preventing him from determining that Defendants are capable of carrying out the death sentence in a lawful manner.

6. Plaintiff alleges that Defendants unconstitutionally rely on Arizona Revised Statutes section 13-757(C), a statute that protects the identity of persons who participate in executions, to hide public governmental activity from him, in violation of his First Amendment right of access to governmental proceedings in the execution context.

7. Plaintiff seeks equitable, injunctive, and declaratory relief to prevent Defendants from carrying out his execution by using pentobarbital from a concealed manufacturer.

8. Plaintiff seeks equitable, injunctive, and declaratory relief to prevent Defendants from carrying out his execution by using pentobarbital from a concealed distributor.

9. Plaintiff seeks equitable, injunctive, and declaratory relief to prevent Defendants from carrying out his execution by using pentobarbital with a concealed expiration date.

10. Plaintiff seeks equitable, injunctive, and declaratory relief to prevent Defendants from carrying out his execution by using pentobarbital with a concealed lot number.

11. Plaintiff seeks equitable, injunctive, and declaratory relief to prevent Defendants from carrying out his execution by using pentobarbital with a concealed National Drug Code.

12. Plaintiff seeks equitable, injunctive, and declaratory relief to prevent Defendants from carrying out his execution by using pentobarbital with a concealed order date.

13. Plaintiff seeks equitable, injunctive, and declaratory relief to prevent Defendants from carrying out his execution by using pentobarbital with a concealed delivery date.

Jurisdiction and Venue

14. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1343 (civil-rights violations), 28 U.S.C. § 2201 (declaratory relief), and 28 U.S.C. § 2202 (injunctive relief). Plaintiff invokes this Court's jurisdiction pursuant to Article III of the United States Constitution, the First and Fourteenth Amendments to the United States Constitution, 42 U.S.C. § 1983.

15. Venue is proper pursuant to 28 U.S.C. § 1391(b). Plaintiff is currently incarcerated at the Arizona State Prison Complex ("ASPC")–Eyman, Browning Unit, 4374 East Butte Avenue, Florence, Arizona, located in this District.

16. All executions conducted by ADC occur at the Central Unit at ASPC–Florence. The events giving rise to this complaint have occurred and/or will occur in this District.

The Parties

17. Plaintiff Robert Glen Jones is a United States citizen and a resident of the State of Arizona. He is currently subject to a sentence of death imposed by the Superior Court of Pima County. Plaintiff is incarcerated at ASPC-Eyman, Browning Unit, in Florence, Arizona.

18. Plaintiff Jones is under a warrant of execution. His execution has been scheduled for October 23, 2013. His execution is scheduled to take place at the Central Unit at ASPC-Florence within the State of Arizona and within this judicial district.

19. Defendant Janice K. Brewer is the Governor of the State of Arizona and is being sued in her official capacity for equitable, injunctive, and declaratory relief.

20. Defendant Charles Ryan is the Director of ADC and is being sued in his official capacity for equitable, injunctive, and declaratory relief.

21. Defendant Ron Credio is the Warden of ASPC-Eyman, where Mr. Schad is incarcerated, and is being sued in his official capacity for equitable, injunctive, and declaratory relief.

22. Defendant Lance Hetmer is the Warden of ASPC-Florence, where Plaintiff will be executed, and is being sued in his official capacity for equitable, injunctive, and declaratory relief.

Exhaustion of Administrative Remedies

23. Plaintiff does not believe that exhaustion is necessary under the Prison Litigation Reform Act ("PLRA"), 42 U.S.C. § 1997e, because this suit does not challenge prison conditions and because there are no available administrative remedies that could address the challenged constitutional

violations. Despite the inapplicability of the PLRA, Plaintiff has exhausted all the remedies available to him in an effort to resolve this issue.

24. Plaintiff, through his counsel, requested certain information from ADC about the drugs ADC intended to use in Plaintiff's execution. Specifically, he asked for information about the drugs' manufacturer and source; the drugs' lot numbers and expiration dates; whether the drugs are from a domestic or foreign source; and whether the drugs have federal Food and Drug Administration (FDA) approval. (Letter from Dale A. Baich to Charles Ryan, July 19, 2013, attached as Ex. A.)

25. In that same letter, Director Ryan was asked to provide documentation indicating that the persons tasked with executing him had authority to handle substances that are classified as controlled substances under the federal Controlled Substances Act. (Ex. A.)

26. On July 30, 2013, Director Ryan responded by asserting that ADC "intends to use unexpired, domestically obtained Pentobarbital" for the execution. (Letter from Charles Ryan to Dale A. Baich, July 30, 2013, attached as Ex. B.)

27. On August 6, 2013, Director Ryan was sent a follow-up letter, asking for the answers to Plaintiff's previous questions, and asking if ADC intended to use Nembutal®, which is the brand name for FDA-approved pentobarbital. (Letter from Dale A. Baich to Charles Ryan, Aug. 6, 2013, attached as Ex. C.)

28. On August 16, 2013, Director Ryan responded, asserting that information about the name of the manufacturer and the source of the drug "is confidential and is not subject to disclosure under A.R.S. § 13-757(C)." (Letter from Charles Ryan to Dale A. Baich, August 16, 2013, attached as Ex. D.)

29. To date, the State has refused to provide Plaintiff with the information he requested regarding the pentobarbital it intends to use in his execution.

30. To date, Director Ryan has refused to provide Plaintiff with evidence that the persons who will execute him are lawfully authorized to handle controlled substances.

Relevant Facts

31. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Complaint as if fully rewritten.

32. Plaintiff was convicted and sentenced to death in Arizona. He sought and was denied relief from his convictions and sentences in state and feredal courts. *See Jones v. Ryan* 691 F.3d 1093, 1095-96 & n.1 (9th Cir. 2012).

33. On August 27, 2013, the Arizona Supreme Court issued a warrant for Plaintiff's execution, setting the date for October 23, 2013.

34. Plaintiff refused to choose his method of execution; therefore, ADC must use lethal injection to execute him. Ariz. Rev. Stat. § 13-757(B).

Arizona's Execution Statute and Execution Protocol

35. Arizona Revised Statutes section 13-757 establishes Arizona's method of execution.

36. Section 13-757(C) protects from public-records requests the identity of "executioners and other persons who participate or perform ancillary functions and any information that would identify those persons . . . ."

37. ADC's current written lethal injection protocol became effective on September 21, 2012. *See* Preparation and Administration of Chemicals, ADC Department Order 710, Attachment D, *available at* http://www.azcorrections.gov/Policies/700/0710.pdf.

38. ADC's current protocol provides that ADC can carry out lethal-injection executions with either sodium pentothal ("sodium thiopental") or pentobarbital.

Federal Drug Laws

39. Drugs are regulated by, *inter alia*, the federal Food, Drug, and Cosmetics Act (FDCA).

40. The FDCA is enforced by the federal Food and Drug Administration (FDA).

41. The FDA requires registered drug establishments to provide the agency with current lists of all drugs the establishments produce for commercial distribution.

42. Each drug produced by registered drug establishments is identified by a unique number called the National Drug Code ("NDC").

43. If a drug is classified as a controlled substance under the federal Controlled Substances Act, the drug is also regulated by the federal Drug Enforcement Agency ("DEA").

44. If a drug is a controlled substance, individuals who wish to handle it must have appropriate registration from the DEA.

45. Sodium thiopental is a controlled substance.

46. Pentobarbital is a controlled substance.

Sodium Thiopental

47. Beginning in 2010, ADC developed a history of using illegitimately obtained controlled-substance drugs in executions.

48. Sodium thiopental is not approved by the FDA.

49. Sodium thiopental does not have an NDC.

50. Sodium thiopental is a Schedule III drug under the federal Controlled Substances Act (CSA).

51. In 2010, ADC's protocol called for lethal injections to be carried out via a three-drug procedure, the first drug of which was sodium thiopental.

52. In September 2010, the State of Arizona scheduled an execution for Jeffrey Landrigan.

53. In 2010, ADC was unable to obtain a domestic source of sodium thiopental, owing to a nationwide shortage of that drug.

54. On October 20, 2010, the State admitted during a hearing before the Arizona Supreme Court that ADC had obtained unexpired sodium thiopental that was not manufactured by a domestic source.

55. In 2010 and 2011, various prisoners on Arizona's death row informed ADC and the courts that ADC had likely violated the CSA and the FDCA when it acquired non-domestic sodium thiopental.

56. In 2010 and 2011, Director Ryan repeatedly avowed in state and federal courts that ADC had complied with all laws in obtaining the non-domestic sodium thiopental.

57. In May 2011, the DEA informed the State that ADC violated the CSA when ADC imported sodium thiopental.

58. ADC used illegitimately obtained sodium thiopental in the execution of Jeffrey Landrigan (October 26, 2010).

59. ADC used illegitimately obtained sodium thiopental in the execution of Eric King (March 29, 2011).

60. In October 2011, ADC's then-Deputy Director provided documents during his deposition in a civil-rights lawsuit that indicated that he ignored counterfeiting and efficacy concerns about imported sodium thiopental.

61. In March 2012, the United States District Court for the District of Columbia found that the importation of sodium thiopental by ADC and departments of corrections in other states violated the FDCA.

62. Non-FDA-approved sodium thiopental is not legally available to departments of corrections.

Pentobarbital

63. FDA-approved pentobarbital is sold under the brand name Nembutal®.

64. Nembutal® has an NDC.

65. Pentobarbital is a Schedule II drug under the Controlled Substances Act.

66. ADC provided Nembutal® procurement records to counsel with the Office of the Federal Public Defender for the District of Arizona (FPD) in August 2011 in litigation unrelated to this matter.

67. According to ADC's August 2011 procurement records, ADC ordered 75g of Nembutal® on September 27, 2010.

68. According to ADC's August 2011 procurement records, the September 2010 purchase was the only supply of Nembutal® ADC possessed at the time it produced those records.

69. According to ADC's August 2011 procurement records, ADC's supply of Nembutal® it purchased in 2010 expired in March 2013.

Legal suppliers of Nembutal®

70. During the time period 2010 (when ADC purchases its supply of Nembutal®) through approximately January 2012, Lundbeck's Nembutal® was the only FDA-approved source of pentobarbital.

71. In July 2011, Lundbeck instituted distribution controls on Nembutal®.

72. Lundbeck's distribution controls established a limited set of distributors authorized to sell Nembutal®.

73. Lundbeck instituted its distribution controls to prevent the legitimate sale of Nembutal® to departments of corrections in states that use lethal injection for capital punishment.

74. In December 2011, Lundbeck announced the sale of its interest in Nembutal® to Akorn.

75. When Akorn purchased Lundbeck's interest in Nembutal®, Akorn kept Lundbeck's distribution controls in place.

76. Currently, Akorn is the only FDA-approved source of pentobarbital.

77. As of July 2011, ADC had no legitimate source from which to purchase Nembutal®.

ADC has obtained a new supply of Nembutal®, but refuses to provide expiration dates and other information about the supply.

78. Last month, ADC produced documents indicating that ADC now has a supply of Nembutal®.

79. On September 17, 2013, the American Civil Liberties Union of Arizona (ACLU) filed a public-records request with ADC, asking for information pertaining to drugs ADC intends to use in Plaintiff's execution, including, *inter alia*, the manufacturer, distributor, lot number, expiration date, and NDC of the drugs.

80. On September 25, 2013, ADC gave certain information to ACLU relating to the pentobarbital ADC intends to use in Plaintiff's execution. (Letter from Dawn Northup to Kelly Flood, Sept. 25, 2013, attached as Ex. E.)

81. ADC's documents demonstrate that ADC ordered 25g of Nembutal®. (Invoice attached to Letter from Dawn Northup to Kelly Flood, Sept. 25, 2013, attached as Ex. E(1).)

82. ADC redacted the month and day on which ADC ordered the Nembutal®, but left the year (2011) unredacted. (Ex. E(1).)

83. ADC redacted the month and day on which the shipment was due, but left the year (2011) unredacted. (Ex. E(1).)

84. ADC redacted the drug's NDC. (Ex. E(1); *see also* Inventory Labels, attached to Letter from Dawn Northup to Kelly Flood, Sept. 25, 2013, attached as Ex. E(2).)

85. ADC either redacted or withheld the expiration dates of the Nembutal®. (Ex. E(2).)

86. ADC either redacted or withheld the lot numbers of the Nembutal®. (Ex. E(2).)

87. ADC redacted the manufacturer name of the Nembutal®. (Ex. E(1) and E(2).)

88. ADC redacted the distributor of the Nembutal®. (Ex. E(1) and E(2).)

89. ADC did not provide information demonstrating that ADC personnel are authorized under federal law to handle controlled substances.

90. ADC claimed that "[t]he information that has been redacted is confidential pursuant to A.R.S. § 13-757(C)." (Ex. E.)

ADC currently refuses to provide the same type of information it has previously provided.

91. In July 2011, in response to a public-records lawsuit, ADC released information about its supply of sodium thiopental.

92. ADC's public-records release included the name of the foreign supplier of the drug.

93. ADC's public-records release included the lot numbers of the drug.

94. ADC's public-records release included the expiration dates of the drug.

95. In July 2011, when ADC provided documents in response to a public-records lawsuit, ADC provided detailed information about its supply of sodium thiopental, including distributor name, lot numbers, and expiration dates.

96. In August 2011, when ADC provided the FPD with lethal-drug procurement records, ADC provided detailed information about its September 2010 supply of Nembutal®.

97. The Nembutal® procurement records include the date the drug was ordered.

98. The Nembutal® procurement records include the date the drug was scheduled for delivery.

99. The Nembutal® procurement records include the drug's NDC.

100. The Nembutal® procurement records include expiration dates of the drug.

101. The Nembutal® procurement records include lot numbers of the drug.

102. The Nembutal® procurement records include photographs of the vials of the drug.

103. The Nembutal® procurement records include photographs of the vials of the drug.

104. The Nembutal® procurement records include photographs of the expiration dates on the boxes of the drug.

105. The Nembutal® procurement records include photographs of the lot numbers on the boxes of the drug.

106. ADC now claims that numerical data and manufacturing information is protected under an Arizona statute protecting the identity of persons participating in executions.

107. Dates on which products are ordered are not people.

108. Dates on which products are ordered do not identify people involved in executions.

109. Dates on which products are due to be delivered are not people.

110. Dates on which products are due to be delivered do not identify people involved in executions.

111. NDCs are not people.

112. NDCs are numbers that do not identify people involved in executions.

113. Expiration dates of drugs are not people.

114. Expiration dates of drugs do not identify people involved in executions.

115. Lot numbers of drugs are not people.

116. Lot numbers of drugs do not identify people involved in executions.

117. The names of manufacturing establishments of drugs are not people.

118. The names of manufacturing establishments of drugs do not identify people involved in executions.

119. The names of drug distribution companies are not people.

120. The names of drug distribution companies do not identify people involved in executions.

121. ADC redacted order dates in order to hide the fact that ADC intends to use expired Nembutal®.

122. On information and belief, ADC redacted delivery dates in order to hide the fact that ADC intends to use expired Nembutal®.

123. On information and belief, ADC redacted the NDC of the Nembutal® in order to hide information that could identify the manufacturer because the manufacturer could verify expiration dates.

124. On information and belief, ADC redacted or withheld expiration dates in order to hide the fact that ADC intends to use expired Nembutal®.

125. On information and belief, ADC redacted or withheld lot numbers because those numbers could be used to determine expiration dates.

126. On information and belief, ADC redacted the manufacturer of the Nembutal® because the manufacturer could verify expiration dates.

127. On information and belief, ADC redacted the distributor of the Nembutal® because the distributor could verify expiration dates.

128. On information and belief, ADC refused to provide information relating to individual DEA authorizations to handle controlled substances because certain members of the execution team are not licensed to handle controlled substances.

Claims for Relief

Claim One: Defendants' deliberate actions in hiding information violates Plaintiff's First Amendment right to be informed about the manner in which the State implements the most serious penalty available in the criminal-justice system.

129. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Complaint as if fully rewritten.

130. Defendants' refusal to provide Plaintiff with information that would enable him to determine how the State intends to execute him denies him his First Amendment right of access to governmental proceedings. S*ee Cal. First Amendment Coal. v. Woodford*, 299 F.3d 868, 873 (9th Cir. 2002) ("It is well-settled that the First Amendment guarantees the public—and the press—a qualified right of access to governmental proceedings."); *id*. at 875 (noting that the public's First Amendment right of access to governmental proceedings extends to executions).

131. Defendants' deliberate concealment of information that would enable Plaintiff to determine how the State intends to carry out the death sentence, including information relating to lethal-injection drugs and the authority of Defendants to handle controlled substances, denies Plaintiff of his First Amendment right of access to governmental proceedings.

132. Defendants' deliberate concealment of information that would enable Plaintiff to determine how the State intends to carry out the death sentence, including information relating to lethal-injection drugs and the authority of Defendants to handle controlled substances, denies Plaintiff of his First Amendment right to be informed about how the State intends to implement the most serious punishment possible: the penalty of death.

Claim Two: Defendants' deliberate actions in hiding information regarding the lethal-injection drugs that they intend to use denies Plaintiff his federal rights to due process and meaningful access to the courts.

133. Plaintiff incorporates by reference every statement and allegation set forth throughout this Complaint as if fully rewritten.

134. The Fourteenth Amendment prohibits a state from depriving "any person of life, liberty, or property, without due process of law." U.S. Const. amend XIV. 214.

135. "[P]risoners have a constitutional right of access to the courts." *See Bounds v. Smith*, 430 U.S. 817, 821 (1977). The "right of access to the courts . . . is founded in the Due Process Clause." *Wolff v. McDonnell*, 418 U.S. 539, 579 (1974).

136. Plaintiff has a liberty interest in assuring that his execution is carried out in a manner consistent with the Eighth Amendment.

137. Defendants' failure to provide Plaintiff with the requested information regarding his scheduled execution and the drug it intends to use has created a virtually insurmountable barrier to the filing and prosecution of a colorable Eighth Amendment claim.

138. By deliberately concealing information from Plaintiff, Defendants have actively prevented Plaintiff from to making a valid assessment of whether he will be executed in a manner that will violated his Eighth Amendment rights. Therefore, Defendants' actions have violated Plaintiff's rights to due process and access to the courts.

Prayer for Relief

WHEREFORE, Plaintiff prays for:

1. Temporary, preliminary, and permanent injunctive relief to enjoin the defendants, their officers, agents, servants, employees, and all persons acting in concert with them from concealing information that is not related to the identification of persons participating in

executions, and that is necessary to ensuring Plaintiff's First Amendment right of access to governmental proceedings, including but not limited to information about

a. The manufacturer of lethal-injection drugs

b. The NDCs of lethal-injection drugs

c. The lot numbers of lethal-injection drugs

d. The expiration dates of lethal-injection drugs

e. Documentation indicating that those who will handle pentobarbital or other controlled substances in the execution have the appropriate DEA authorization to do so.

2. Appropriate and necessary discovery and an evidentiary hearing to permit Plaintiff to prove his constitutional claims; and

3. Any such other relief as the Court deems just and proper.

Respectfully submitted this 3rd day of October 2013.

Jon M. Sands
Federal Public Defender
Dale A. Baich
Robin C. Konrad
Assistant Federal Public Defenders

s/ Dale A. Baich
Counsel for Plaintiff

Exhibit A

Office of the
FEDERAL PUBLIC DEFENDER
for the District of Arizona
Capital Habeas Unit

Jon M. Sands
Federal Public Defender

direct line: 602-382-2816
email: dale_baich@fd.org

July 19, 2013

Mr. Charles Ryan, Director
Arizona Department of Corrections
1601 West Jefferson
Phoenix, AZ 85007

Dear Director Ryan:

I am writing to you on behalf of Robert Jones and Ed Schad, for whom the State has filed motions for warrants of execution.[1] In order for me to properly advise Messrs. Jones and Schad about their potential executions, I request that you provide me with the following information pertaining to the lethal substance that Arizona Department of Corrections (ADC) intends to use in his execution and ADC's authorization to use controlled substances in executions.

1. ADC Department Order 710 lists pentobarbital and sodium thiopental as the two default lethal substances used for executions in the one-drug protocol.[2] Because I believe that ADC does not have a current supply of pentobarbital[3] or

[1] Mot. for Warrant of Execution, *State v. Jones*, No. CR-98-0537-AP June 25, 2013; Mot. for Warrant of Execution, *State v. Schad*, No. CR-13-0058-PC June 25, 2013.

[2] *See* ADC Dep't Order 710, Attachment D section C, effective date Sept. 21, 2012.

[3] On September 27, 2010, ADC purchased a supply of Nembutal. *See* Defendant's Disclosures, Bates No. 01985 DFS' 26(a)(1) Disclosures and Responses to RFP's, (Nembutal Purchase Order), *West v. Brewer*, No. 2:11-cv-01409-NVW (D. Ariz.), August 19, 2011.

That supply expired in March 2013. *See* Defendant's Disclosures, Bates No. 01973-01978 DPS' 26(a)(1) Disclosures and Responses to RFP's, (Photographs of Nembutal Supply), *West v. Brewer*, No. 2:11-cv-01409-NVW (D. Ariz.), August 1, 2011.

Additionally, Nembutal has not been available to prisons in states that have capital punishment since July 1, 2011. *See* Lundbeck statement, *Lundbeck overhauls pentobarbital distribution program to restrict misuse*, http://investor.lundbeck.com/releasedetail.cfm?ReleaseID=605775 (last visited May 25, 2012).

sodium thiopental,[4] please identify the name of each lethal substance[5] ADC intends to use for the two executions now, so the clients can be properly advised. As you are aware, addressing these issues at the last minute is extremely difficult.[6]

2. Please provide me with the name of the manufacturer; the source of the substance, including whether the substance is from a domestic or foreign source; proof that the substance is approved by the Food and Drug Administration (FDA); and the legal authority for your acquisition and possession of the lethal substance ADC intends to use.

3. If ADC intends to use a substance that is not FDA-approved, please provide the source of that drug. In particular, if ADC intends to use a compounded substance, please identify the name of the pharmacist or other personnel who will provide the compounded substance.

4. Please provide me with the credentials[7] of each IV Team member with respect to any Drug Enforcement Agency (DEA) registrations that authorize IV Team members to handle controlled substances.

---

[4] You previously wrote ADC surrendered its supply of sodium thiopental to the Drug Enforcement Agency on February 2, 2012. Additionally, importation of additional supplies of sodium thiopental have been prohibited since March of 2012, under *Beaty v. FDA,* 853 F. Supp. 2d 30, 35 (D.D.C. 2012) *appeal filed, sub nom. Cook v. FDA*, No. 1:11-cv-00289-RJL (D.C. Cir.), *and argued* March 25, 2013.

[5] Because I do not know how many lethal substances the ADC intends to use, I use "substance" in this letter to refer to one or multiple substances.

[6] *See Towery v. Brewer*, 672 F.3d 650, 652-53 (9th Cir. 2012) (noting that the State of Arizona's consistent approach to change protocols on the eve of executions forces the court to hear appeals at the "in the waning hours before executions" and cannot continue).

[7] ADC Dep't Order 710, section 710.02, 1.2.5.2.

The information requested is critical in advising the clients regarding their pending executions. Your prompt response will be greatly appreciated.

Sincerely,

Dale A. Baich
Supervisor
Capital Habeas Unit

DAB/clh

cc: Tim Gabrielsen
Denise I. Young
Kelley J. Henry

Exhibit B

Arizona Department of Corrections

1601 WEST JEFFERSON
PHOENIX, ARIZONA 85007
(602) 542-5497
www.azcorrections.gov

JANICE K. BREWER
GOVERNOR

CHARLES L. RYAN
DIRECTOR

RECEIVED
AUG 01 2013
Federal Public Defender
Capital Habeas Unit

July 30, 2013

Dale Baich, Supervisor
Capital Habeas Unit
Office of the Federal Public Defender
850 W. Adams St., Suite 201
Phoenix, AZ 85007

Re: Warrants of Execution for:
Robert Jones, ADC #070566 and Edward Schad, ADC #040496

Dear Mr. Baich:

In response to your letter of July 19, 2013, inquiring about the name and source of the drug the Arizona Department of Corrections ("ADC") intends to use for these executions, the ADC will follow the one-drug protocol set forth in Department Order 710 (Chart A, Attachment D). The ADC intends to use unexpired, domestically obtained Pentobarbital for these executions.

Sincerely,

Charles L. Ryan
Director

CLR/dn/kp

cc: Jeff Hood, Deputy Director
Robert Patton, Division Director, Prison Operations
Dawn Northup, General Counsel
Jeff Zick, Division Chief, Capital Appeals, Attorney General's Office

Exhibit C

Office of the
FEDERAL PUBLIC DEFENDER
for the District of Arizona
Capital Habeas Unit

Jon M. Sands
Federal Public Defender

direct line: 602-382-2816
email: dale_baich@fd.org

August 6, 2013

Mr. Charles Ryan, Director
Arizona Department of Corrections
1601 West Jefferson
Phoenix, AZ 85007

Dear Director Ryan:

Thank you for your recent response to my letter regarding the name of the drug that the Arizona Department of Corrections (ADC) intends to use for Robert Glen Jones Jr.'s and Edward Schad's potential executions. I am writing to follow up on some of the unresolved issues from my original letter.

You stated in your response that "ADC intends to use unexpired, domestically obtained Pentobarbital" for the executions of Messrs. Jones and Schad. However, you did not provide me with the name of the manufacturer, the source of the pentobarbital, and the expiration date of the drug. For instance, if Hospira was the manufacturer for Lundbeck, and the brand name of the drug was Nembutal,[1] Messrs. Jones and Schad would know that the pentobarbital was FDA-approved.[2]

If ADC intends to use a substance that is not FDA-approved, please provide the source of that drug, the manufacturer, and the expiration date. In addition, if ADC intends to use a compounded substance, please identify the name of the pharmacist or other personnel

[1] On August 1, 2013, the State of Florida disclosed that it acquired Nembutal manufactured by Hospira for Lundbeck on June 9 and 15, 2011, that has expiration dates of September 30 and November 30, 2013. *See* Dep't of Corr. Answer to Interrogatory, *Ferguson v. Palmer*, No. 3:12-cv-0136-UAMH-JBT (M.D. Fla., Aug. 1, 2013) (ECF No. 52).

[2] You stated that FDA approval of the drugs used to carry out execution makes a difference. "If it was not FDA approved, then we may not [] acquire[] that." *See* Dep. of Charles Ryan, at 208:15-21, Oct. 14, 2011, *West v. Brewer*, No. 2:11-cv-01409-NVW (D. Ariz.).

who will provide the compounded substance, as well as the source(s) of the ingredients that the compounder uses.

As you know, pentobarbital is a Schedule II drug. Accordingly, please provide me with the credentials of each IV Team member with respect to any Drug Enforcement Agency (DEA) registrations that authorize IV Team members to handle controlled substances.

Again, I appreciate your attention to these questions. Your prompt response will be greatly appreciated.

Sincerely,

Dale A. Baich
Supervisor
Capital Habeas Unit

DAB/clh

cc: Tim Gabrielsen
Denise I. Young
Kelley J. Henry
Jeff Hood, Deputy Director
Robert Patton, Division Director, Prison Operations
Dawn Northup, General Counsel
Jeff Zick, Division Chief, Capital Appeals, Attorney General's Office

Exhibit D

Arizona Department of Corrections

1601 WEST JEFFERSON
PHOENIX, ARIZONA 85007
(602) 542-5497
www.azcorrections.gov

JANICE K. BREWER
GOVERNOR

CHARLES L. RYAN
DIRECTOR

August 16, 2013

Dale Baich, Supervisor
Capital Habeas Unit
Office of the Federal Public Defender
850 W. Adams Street, Suite 201
Phoenix, AZ 85007

Dear Mr. Baich:

In response to your letter of August 6, 2013, requesting the name of the manufacturer and the source of the drug the Arizona Department of Corrections ("ADC") intends to use for the executions of inmates Robert Jones (#070566) and Edward Schad (#040496), that information is confidential and is not subject to disclosure under A.R.S. § 13-757(C). As I reiterated in my letter of July 30, 2013, ADC intends to use the one-drug protocol set forth in Chart A, Attachment D of Department Order ("DO") 710. The protocol to be used for the anticipated executions of inmates Jones and Schad has not changed since ADC published changes to DO 710 in September, 2012. As you know, these changes ultimately led to the Plaintiffs in *Towery v. Brewer*, CV-00245-NVW entering a stipulated dismissal of their Complaint, challenging the constitutionality of Arizona's execution protocol. Similarly, the credentials of the IV team remain the same and are clearly stated in DO 710, Section 1.2.5.

Sincerely,

Charles L. Ryan
Director

CLR/DN/kp

cc: Jeff Hood, Deputy Director
Robert Patton, Division Director, Prison Operations
Dawn Northup, General Counsel
Jeff Zick, Division Chief, Capital Appeals, Attorney General's Office
CLR83336473

RECEIVED
AUG 19 2013
FEDERAL PUBLIC DEFENDER
CAPITAL HABEAS UNIT

Exhibit E

Arizona Department of Corrections

1601 WEST JEFFERSON
PHOENIX, ARIZONA 85007
(602) 542-5497
www.azcorrections.gov

JANICE K. BREWER
GOVERNOR

CHARLES L. RYAN
DIRECTOR

Sent Via E-mail

September 25, 2013

Kelly Flood
Staff Attorney
ACLU of Arizona
P.O. Box 17148
Phoenix, AZ 85011

Re: Public Records Request

Dear Ms. Flood:

Thank you for clarifying your September 17, 2013 public records request. ADC disagrees with your assertion that any portion of the Federal District Court's decision in *Landrigan v. Brewer*, 2010 WL 4269559, D. Ariz. (2010), remains intact following the United States Supreme Court's decision in *Brewer v. Landrigan* ___ U.S. ___, 131 S. Ct. 445 (2010), vacating that decision. Federal law does not compel the ADC to disclose information that is deemed confidential by state statute.

Attached is an additional, redacted record responsive to your request. The information that has been redacted is confidential pursuant to A.R.S. § 13-757(C). The attached record, together with the records previously sent on September 20, 2013, are the complete records in ADC's possession that are responsive to your public records request.

Sincerely,

Dawn Northup
General Counsel

cc: Director Charles Ryan
Jeff Hood, Deputy Director
Robert Patton, Division Director, Prison Operations
Jeff Zick, Assistant Attorney General
Jon Anderson, Assistant Attorney General

Exhibit E(1)

S [redacted]

[redacted]

DEA [redacted] FED ID [redacted]

PAGE 1 OF 1 ROUTE/STOP [redacted]

DV

CUST. NO.	DATE	ORIGINAL INVOICE
[redacted]	[redacted]/11	[redacted]
REG NO.	CUST. DEA NO.	ORDER NO.	CUSTOMER P.O. NUMBER
EXEMPT	FA2203571	[redacted]	
DEPT.	ORDER DATE	CONF. NO.	
	[redacted]/11	[redacted]	

BILL TO
ARIZONASTATEPRISON -FLORENCE
WARDEN-CARSON MCWILLIAMS ****
1305 BUTTE AVENUE
FLORENCE, AZ 85232

SHIP TO
ARIZONASTATEPRISON -FLORENCE
WARDEN-CARSON MCWILLIAMS ****
1305 BUTTE AVENUE
FLORENCE, AZ 85232

FORM [redacted]

ITEM NUMBER	NDC/UPC	QTY ORDERED	QTY SHIPPED	U/M	DESCRIPTION	SIZE	FORM	CLASS	REF			UNIT PRICE	EXTENSION	NOTE CODE
[redacted]		10	10	EA	NEMBUTAL SOD 50MG/ML 50ML C2	1	MD	2	[redacted]			900.77	900770	T
	PO#: 1													
			10		PIECES SHIPPED							SUBTOT	900770	
			10		TOTAL PIECES SHIPPED									
					S U M M A R Y									
					Total RX				9007.70					
					Total REF				0.275.90					
					NET AMOUNT				9007.70					
	INVOICE SETUP DATE: [redacted]/2011													
	REMIT TO [redacted]													

FOR DELIVERY [redacted]/11

[redacted]/11
DUE DATE

900770

Note Codes:			
T	Taxable	CT	Contract
G	Generic Sub	SN	Special Net
PP	PharmPak Discount	SP	Special Pricing

Omit Codes:		
1 Mfg. B. O.	4 Not stocked	7 Drug recal
2 Whse. out	5 Mfg. disc.	8 New item/stock unavail.
3 Mfg. out	6 Whse. disc.	9 Restricted item

If this invoice reflects any discounted prices, credits, or rebates or if price reductions are subsequently earned and paid with respect to the merchandise/services described herein, then federal law may require disclosure on the price reduction on your claim or cost reports for Medicare or Medicaid reimbursement under 42 U.S.C. 1320(a)-7b.

Customer is a final dispenser that does not and will not redistribute prescription pharmaceuticals into to the secondary market

[redacted]

Case 2:13-cv-02001-ROS Document 8-1 Filed 10/03/13 Page 31 of 43

Exhibit E(2)

There are perforations between each row of labels. Remove perforation at left edge before tearing between rows.

Remove this Perforation first

Page 1

** ********************************

***************** *** TOTE# [redacted] Container Num [redacted]

***************** ARIZONASTATEPRISON - [redacted]

***************** DATE- [redacted]/2011 INV 6134728

***************** RX-711 OTC-711

***************** CUST PO

***************** ********************************

[redacted]/11 RX
NEMBUTAL SOD 50
MG/ML 50ML C2
10 1 MD
NDC [redacted]

[redacted]

NEMBUTAL
[redacted]11
I#[redacted]
1 50 MG
[redacted] 10
90077

NEMBUTAL
[redacted]11
I#[redacted]
1 50 MG
[redacted] 10
90077

NEMBUTAL
[redacted]11
I#[redacted]
1 50 MG
[redacted] 10
90077

NEMBUTAL
[redacted]11
I#[redacted]
1 50 MG
[redacted] 10
90077

NEMBUTAL
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I#[redacted]
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I#[redacted]
1 50 MG
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90077

NEMBUTAL
[redacted]11
I#[redacted]
1 50 MG
[redacted] 10
90077

[redacted]

[redacted]

[redacted]

[redacted]

Cust#

Exhibit E(3)

[redacted]

Nembutal® Sodium Solution
(pentobarbital sodium injection, USP)
℞ only

[redacted]

Vials
DO NOT USE IF MATERIAL HAS PRECIPITATED

DESCRIPTION

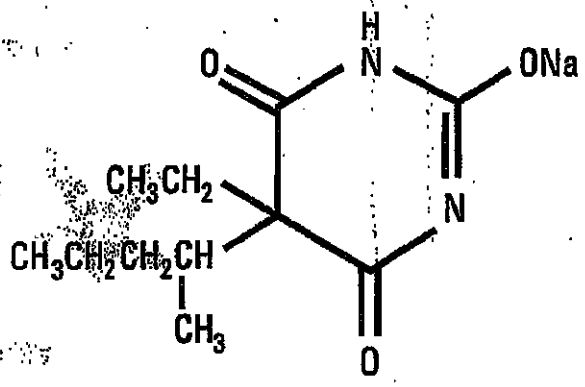
The barbiturates are nonselective central nervous system depressants which are primarily used as sedative hypnotics and also anticonvulsants in subhypnotic doses. The barbiturates and their sodium salts are subject to control under the Federal Controlled Substances Act (See "Drug Abuse and Dependence" section).

The sodium salts of amobarbital, pentobarbital, phenobarbital, and secobarbital are available as sterile parenteral solutions.

Barbiturates are substituted pyrimidine derivatives in which the basic structure common to these drugs is barbituric acid, a substance which has no central nervous system (CNS) activity. CNS activity is obtained by substituting alkyl, alkenyl, or aryl groups on the pyrimidine ring.

NEMBUTAL Sodium Solution (pentobarbital sodium injection) is a sterile solution for intravenous or intramuscular injection. Each mL contains pentobarbital sodium 50 mg, in a vehicle of propylene glycol, 40%, alcohol, 10% and water for injection, to volume. The pH is adjusted to approximately 9.5 with hydrochloric acid and/or sodium hydroxide.

NEMBUTAL Sodium is a short-acting barbiturate, chemically designated as sodium 5-ethyl-5-(1-methylbutyl) barbiturate. The structural formula for pentobarbital sodium is:



The sodium salt occurs as a white, slightly bitter powder which is freely soluble in water and alcohol but practically insoluble in benzene and ether.

CLINICAL PHARMACOLOGY

Barbiturates are capable of producing all levels of CNS mood alteration from excitation to mild sedation, to hypnosis, and deep coma. Overdosage can produce death. In high enough therapeutic doses, barbiturates induce anesthesia.

barbiturates induce anesthesia.

Barbiturates depress the sensory cortex, decrease motor activity, alter cerebellar function, and produce drowsiness, sedation, and hypnosis.

Barbiturate-induced sleep differs from physiological sleep. Sleep laboratory studies have demonstrated that barbiturates reduce the amount of time spent in the rapid eye movement (REM) phase of sleep or dreaming stage. Also, Stages III and IV sleep are decreased. Following abrupt cessation of barbiturates used regularly, patients may experience markedly increased dreaming, nightmares, and/or insomnia. Therefore, withdrawal of a single therapeutic dose over 5 or 6 days has been recommended to lessen the REM rebound and disturbed sleep which contribute to drug withdrawal syndrome (for example, decrease the dose from 3 to 2 doses a day for 1 week).

In studies, secobarbital sodium and pentobarbital sodium have been found to lose most of their effectiveness for both inducing and maintaining sleep by the end of 2 weeks of continued drug administration at fixed doses. The short-, intermediate-, and, to a lesser degree, long-acting barbiturates have been widely prescribed for treating insomnia. Although the clinical literature abounds with claims that the short-acting barbiturates are superior for producing sleep while the intermediate-acting compounds are more effective in maintaining sleep, controlled studies have failed to demonstrate these differential effects. Therefore, as sleep medications, the barbiturates are of limited value beyond short-term use.

Barbiturates have little analgesic action at subanesthetic doses. Rather, in subanesthetic doses these drugs may increase the reaction to painful stimuli. All barbiturates exhibit anticonvulsant activity in anesthetic doses. However, of the drugs in this class, only phenobarbital, mephobarbital, and metharbital have been clinically demonstrated to be effective as oral anticonvulsants in subhypnotic doses.

Barbiturates are respiratory depressants. The degree of respiratory depression is dependent upon dose. With hypnotic doses, respiratory depression produced by barbiturates is similar to that which occurs during physiologic sleep with slight decrease in blood pressure and heart rate.

Studies in laboratory animals have shown that barbiturates cause reduction in the tone and contractility of the uterus, ureters, and urinary bladder. However, concentrations of the drugs required to produce this effect in humans are not reached with sedative-hypnotic doses.

Barbiturates do not impair normal hepatic function, but have been shown to induce liver microsomal enzymes, thus increasing and/or altering the metabolism of barbiturates and other drugs. (See "Precautions—*Drug Interactions*" section).

Pharmacokinetics:

Barbiturates are absorbed in varying degrees following oral, rectal, or parenteral administration. The salts are more rapidly absorbed than are the acids.

The onset of action for oral or rectal administration varies from 20 to 60 minutes. For IM administration, the onset of action is slightly faster. Following IV administration, the onset of action ranges from almost immediately for pentobarbital sodium to 5 minutes for phenobarbital sodium. Maximal CNS depression may not occur until 15 minutes or more after IV administration for phenobarbital sodium.

Duration of action, which is related to the rate at which the barbiturates are redistributed throughout the body, varies among persons and in the same person from time to time.

No studies have demonstrated that the different routes of administration are equivalent with respect to bioavailability.

Barbiturates are weak acids that are absorbed and rapidly distributed to all tissues and fluids with high concentrations in the brain, liver, and kidneys. Lipid solubility of the barbiturates is the dominant factor in their distribution within the body. The more lipid soluble the barbiturate, the more rapidly it penetrates all tissues of the body. Barbiturates are bound to plasma and tissue proteins to a varying degree with the degree of binding increasing directly as a function of lipid solubility.

Phenobarbital has the lowest lipid solubility, lowest plasma binding, lowest brain protein binding, the longest delay in onset of activity, and the longest duration of action. At the opposite extreme is secobarbital which has the highest lipid solubility, plasma protein binding, brain protein binding, the shortest delay in onset of activity, and the shortest duration of action. Butabarbital is classified as an intermediate barbiturate.

The plasma half-life for pentobarbital in adults is 15 to 50 hours and appears to be dose dependent.

Barbiturates are metabolized primarily by the hepatic microsomal enzyme system, and the metabolic products are excreted in the urine, and less commonly, in the feces. Approximately 25 to 50 percent of a dose of aprobarbital or phenobarbital is eliminated unchanged in the urine, whereas the amount of other barbiturates excreted unchanged in the urine is negligible. The excretion of unmetabolized barbiturate is one feature that distinguishes the long-acting category from those belonging to other categories which

one feature that distinguishes the long-acting category from those belonging to other categories which are almost entirely metabolized. The inactive metabolites of the barbiturates are excreted as conjugates of glucuronic acid.

INDICATIONS AND USAGE

Parenteral:

a. Sedatives.

b. Hypnotics, for the short-term treatment of insomnia, since they appear to lose their effectiveness for sleep induction and sleep maintenance after 2 weeks (See "Clinical Pharmacology" section).

c. Preanesthetics.

d. Anticonvulsant, in anesthetic doses, in the emergency control of certain acute convulsive episodes, e.g., those associated with status epilepticus, cholera, eclampsia, meningitis, tetanus, and toxic reactions to strychnine or local anesthetics.

CONTRAINDICATIONS

Barbiturates are contraindicated in patients with known barbiturate sensitivity. Barbiturates are also contraindicated in patients with a history of manifest or latent porphyria.

WARNINGS

1. *Habit forming:* Barbiturates may be habit forming. Tolerance, psychological and physical dependence may occur with continued use. (See "Drug Abuse and Dependence" and "Pharmacokinetics" sections). Patients who have psychological dependence on barbiturates may increase the dosage or decrease the dosage interval without consulting a physician and may subsequently develop a physical dependence on barbiturates. To minimize the possibility of overdosage or the development of dependence, the prescribing and dispensing of sedative-hypnotic barbiturates should be limited to the amount required for the interval until the next appointment. Abrupt cessation after prolonged use in the dependent person may result in withdrawal symptoms, including delirium, convulsions, and possibly death. Barbiturates should be withdrawn gradually from any patient known to be taking excessive dosage over long periods of time. (See "Drug Abuse and Dependence" section).
2. *IV administration:* Too rapid administration may cause respiratory depression, apnea, laryngospasm, or vasodilation with fall in blood pressure.
3. *Acute or chronic pain:* Caution should be exercised when barbiturates are administered to patients with acute or chronic pain, because paradoxical excitement could be induced or important symptoms could be masked. However, the use of barbiturates as sedatives in the postoperative surgical period and as adjuncts to cancer chemotherapy is well established.
4. *Use in pregnancy:* Barbiturates can cause fetal damage when administered to a pregnant woman. Retrospective, case-controlled studies have suggested a connection between the maternal consumption of barbiturates and a higher than expected incidence of fetal abnormalities. Following oral or parenteral administration, barbiturates readily cross the placental barrier and are distributed throughout fetal tissues with highest concentrations found in the placenta, fetal liver, and brain. Fetal blood levels approach maternal blood levels following parenteral administration.

   Withdrawal symptoms occur in infants born to mothers who receive barbiturates throughout the last trimester of pregnancy. (See "Drug Abuse and Dependence" section). If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.
5. *Synergistic effects:* The concomitant use of alcohol or other CNS depressants may produce additive CNS depressant effects.

PRECAUTIONS

General:

Barbiturates may be habit forming. Tolerance and psychological and physical dependence may occur with continuing use. (See "Drug Abuse and Dependence" section). Barbiturates should be administered with caution, if at all, to patients who are mentally depressed, have suicidal tendencies, or a history of drug abuse.

Elderly or debilitated patients may react to barbiturates with marked excitement, depression, and confusion. In some persons, barbiturates repeatedly produce excitement rather than depression.

In patients with hepatic damage, barbiturates should be administered with caution and initially in reduced doses. Barbiturates should not be administered to patients showing the premonitory signs of hepatic coma.

Parenteral solutions of barbiturates are highly alkaline. Therefore, extreme care should be taken to avoid perivascular extravasation or intra-arterial injection. Extravascular injection may cause local tissue damage with subsequent necrosis; consequences of intra-arterial injection may vary from transient pain to gangrene of the limb. Any complaint of pain in the limb warrants stopping the injection.

Information for the patient:

Practitioners should give the following information and instructions to patients receiving barbiturates.

Practitioners should give the following information and instructions to patients receiving barbiturates.

1. The use of barbiturates carries with it an associated risk of psychological and/or physical dependence. The patient should be warned against increasing the dose of the drug without consulting a physician.
2. Barbiturates may impair mental and/or physical abilities required for the performance of potentially hazardous tasks (e.g., driving, operating machinery, etc.).
3. Alcohol should not be consumed while taking barbiturates. Concurrent use of the barbiturates with other CNS depressants (e.g., alcohol, narcotics, tranquilizers, and antihistamines) may result in additional CNS depressant effects.

Laboratory tests:

Prolonged therapy with barbiturates should be accompanied by periodic laboratory evaluation of organ systems, including hematopoietic, renal, and hepatic systems. (See "Precautions-*General*" and "Adverse Reactions" sections).

Drug Interactions:

Most reports of clinically significant drug interactions occurring with the barbiturates have involved phenobarbital. However, the application of these data to other barbiturates appears valid and warrants serial blood level determinations of the relevant drugs when there are multiple therapies.

1. *Anticoagulants:* Phenobarbital lowers the plasma levels of dicumarol (name previously used: bishydroxycoumarin) and causes a decrease in anticoagulant activity as measured by the prothrombin time. Barbiturates can induce hepatic microsomal enzymes resulting in increased metabolism and decreased anticoagulant response of oral anticoagulants (e.g., warfarin, acenocoumarol, dicumarol, and phenprocoumon). Patients stabilized on anticoagulant therapy may require dosage adjustments if barbiturates are added to or withdrawn from their dosage regimen.
2. *Corticosteroids:* Barbiturates appear to enhance the metabolism of exogenous corticosteroids probably through the induction of hepatic microsomal enzymes. Patients stabilized on corticosterold therapy may require dosage adjustments if barbiturates are added to or withdrawn from their dosage regimen.
3. *Griseofulvin:* Phenobarbital appears to interfere with the absorption of orally administered griseofulvin, thus decreasing its blood level. The effect of the resultant decreased blood levels of griseofulvin on therapeutic response has not been established. However, it would be preferable to avoid concomitant administration of these drugs.
4. *Doxycycline:* Phenobarbital has been shown to shorten the half-life of doxycycline for as long as 2 weeks after barbiturate therapy is discontinued.

   This mechanism is probably through the induction of hepatic microsomal enzymes that metabolize the antibiotic. If phenobarbital and doxycycline are administered concurrently, the clinical response to doxycycline should be monitored closely.
5. *Phenytoin, sodium valproate, valproic acid:* The effect of barbiturates on the metabolism of phenytoin appears to be variable. Some investigators report an accelerating effect, while others report no effect. Because the effect of barbiturates on the metabolism of phenytoin is not predictable, phenytoin and barbiturate blood levels should be monitored more frequently if these drugs are given concurrently. Sodium valproate and valproic acid appear to decrease barbiturate metabolism; therefore, barbiturate blood levels should be monitored and appropriate dosage adjustments made as indicated.
6. *Central nervous system depressants:* The concomitant use of other central nervous system depressants, including other sedatives or hypnotics, antihistamines, tranquilizers, or alcohol, may produce additive depressant effects.
7. *Monoamine oxidase inhibitors (MAOI):* MAOI prolong the effects of barbiturates probably because metabolism of the barbiturate is inhibited.
8. *Estradiol, estrone, progesterone and other steroidal hormones:* Pretreatment with or concurrent administration of phenobarbital may decrease the effect of estradiol by increasing its metabolism. There have been reports of patients treated with antiepileptic drugs (e.g., phenobarbital) who became pregnant while taking oral contraceptives. An alternate contraceptive method might be suggested to women taking phenobarbital.

Carcinogenesis:

1. *Animal data.* Phenobarbital sodium is carcinogenic in mice and rats after lifetime administration. In mice, it produced benign and malignant liver cell tumors. In rats, benign liver cell tumors were observed very late in life.
2. *Human data.* In a 29-year epidemiological study of 9,136 patients who were treated on an

very late in life.

2. *Human data.* In a 29-year epidemiological study of 9,136 patients who were treated on an anticonvulsant protocol that included phenobarbital, results indicated a higher than normal incidence of hepatic carcinoma. Previously, some of these patients were treated with thorotrast, a drug that is known to produce hepatic carcinomas. Thus, this study did not provide sufficient evidence that phenobarbital sodium is carcinogenic in humans.

Data from one retrospective study of 235 children in which the types of barbiturates are not identified suggested an association between exposure to barbiturates prenatally and an increased incidence of brain tumor. (Gold, E., et al., "Increased Risk of Brain Tumors in Children Exposed to Barbiturates," Journal of National Cancer Institute, 61:1031-1034, 1978).

Pregnancy:

1. *Teratogenic effects.* Pregnancy Category D—See "Warnings—Use in Pregnancy" section.

2. *Nonteratogenic effects.* Reports of infants suffering from long-term barbiturate exposure *in utero* included the acute withdrawal syndrome of seizures and hyperirritability from birth to a delayed onset of up to 14 days. (See "Drug Abuse and Dependence" section).

Labor and delivery:

Hypnotic doses of these barbiturates do not appear to significantly impair uterine activity during labor. Full anesthetic doses of barbiturates decrease the force and frequency of uterine contractions. Administration of sedative-hypnotic barbiturates to the mother during labor may result in respiratory depression in the newborn. Premature infants are particularly susceptible to the depressant effects of barbiturates. If barbiturates are used during labor and delivery, resuscitation equipment should be available.

Data are currently not available to evaluate the effect of these barbiturates when forceps delivery or other intervention is necessary. Also, data are not available to determine the effect of these barbiturates on the later growth, development, and functional maturation of the child.

Nursing mothers:

Caution should be exercised when a barbiturate is administered to a nursing woman since small amounts of barbiturates are excreted in the milk.

Pediatric Use:

No adequate well-controlled studies have been conducted in pediatric patients; however, safety and effectiveness of pentobarbital in pediatric patients is supported by numerous studies and case reports cited in the literature.

Pediatric dosing information for NEMBUTAL is described in the DOSAGE and ADMINISTRATION section.

Geriatric Use:

Clinical studies of NEMBUTAL have not included sufficient numbers of subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

Elderly patients may react to barbiturates with marked excitement, depression, and confusion. In some persons, barbiturates repeatedly produce excitement rather than depression. Dosage should be reduced in the elderly because these patients may be more sensitive to barbiturates.

ADVERSE REACTIONS

The following adverse reactions and their incidence were compiled from surveillance of thousands of hospitalized patients. Because such patients may be less aware of certain of the milder adverse effects of barbiturates, the incidence of these reactions may be somewhat higher in fully ambulatory patients.

More than 1 in 100 patients. The most common adverse reaction estimated to occur at a rate of 1 to 3 patients per 100 is: *Nervous System:* Somnolence.

Less than 1 in 100 patients. Adverse reactions estimated to occur at a rate of less than 1 in 100 patients listed below, grouped by organ system, and by decreasing order of occurrence are:

Nervous system: Agitation, confusion, hyperkinesia, ataxia, CNS depression, nightmares, nervousness, psychiatric disturbance, hallucinations, insomnia, anxiety, dizziness, thinking abnormality.

Respiratory system: Hypoventilation, apnea.

Cardiovascular system: Bradycardia, hypotension, syncope.

Digestive system: Nausea, vomiting, constipation.

Other reported reactions: Headache, injection site reactions, hypersensitivity reactions (angioedema, skin rashes, exfoliative dermatitis), fever, liver damage, megaloblastic anemia following chronic phenobarbital use.

To report SUSPECTED ADVERSE REACTIONS, contact Lundbeck Inc. at 1-800-455-1141 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG ABUSE AND DEPENDENCE

Pentobarbital sodium injection is subject to control by the Federal Controlled Substances Act under DEA schedule II.

Barbiturates may be habit forming. Tolerance, psychological dependence, and physical dependence may occur especially following prolonged use of high doses of barbiturates. Daily administration in excess of 400 milligrams (mg) of pentobarbital or secobarbital for approximately 90 days is likely to produce some degree of physical dependence. A dosage of from 600 to 800 mg taken for at least 35 days is sufficient to produce withdrawal seizures. The average daily dose for the barbiturate addict is usually about 1.5 grams. As tolerance to barbiturates develops, the amount needed to maintain the same level of intoxication increases; tolerance to a fatal dosage, however, does not increase more than two-fold. As this

intoxication increases; tolerance to a fatal dosage, however, does not increase more than two-fold. As this occurs, the margin between an intoxicating dosage and fatal dosage becomes smaller.

Symptoms of acute intoxication with barbiturates include unsteady gait, slurred speech, and sustained nystagmus. Mental signs of chronic intoxication include confusion, poor judgment, irritability, insomnia, and somatic complaints.

Symptoms of barbiturate dependence are similar to those of chronic alcoholism. If an individual appears to be intoxicated with alcohol to a degree that is radically disproportionate to the amount of alcohol in his or her blood the use of barbiturates should be suspected. The lethal dose of a barbiturate is far less if alcohol is also ingested.

The symptoms of barbiturate withdrawal can be severe and may cause death. Minor withdrawal symptoms may appear 8 to 12 hours after the last dose of a barbiturate. These symptoms usually appear in the following order: anxiety, muscle twitching, tremor of hands and fingers, progressive weakness, dizziness, distortion in visual perception, nausea, vomiting, insomnia, and orthostatic hypotension. Major withdrawal symptoms (convulsions and delirium) may occur within 16 hours and last up to 5 days after abrupt cessation of these drugs. Intensity of withdrawal symptoms gradually declines over a period of approximately 15 days. Individuals susceptible to barbiturate abuse and dependence include alcoholics and opiate abusers, as well as other sedative-hypnotic and amphetamine abusers.

Drug dependence to barbiturates arises from repeated administration of a barbiturate or agent with barbiturate-like effect on a continuous basis, generally in amounts exceeding therapeutic dose levels. The characteristics of drug dependence to barbiturates include: (a) a strong desire or need to continue taking the drug; (b) a tendency to increase the dose; (c) a psychic dependence on the effects of the drug related to subjective and individual appreciation of those effects; and (d) a physical dependence on the effects of the drug requiring its presence for maintenance of homeostasis and resulting in a definite, characteristic, and self-limited abstinence syndrome when the drug is withdrawn.

Treatment of barbiturate dependence consists of cautious and gradual withdrawal of the drug. Barbiturate-dependent patients can be withdrawn by using a number of different withdrawal regimens. In all cases withdrawal takes an extended period of time. One method involves substituting a 30 mg dose of phenobarbital for each 100 to 200 mg dose of barbiturate that the patient has been taking. The total daily amount of phenobarbital is then administered in 3 to 4 divided doses, not to exceed 600 mg daily. Should signs of withdrawal occur on the first day of treatment, a loading dose of 100 to 200 mg of phenobarbital may be administered IM in addition to the oral dose. After stabilization on phenobarbital, the total daily dose is decreased by 30 mg a day as long as withdrawal is proceeding smoothly. A modification of this regimen involves initiating treatment at the patient's regular dosage level and decreasing the daily dosage by 10 percent if tolerated by the patient.

Infants physically dependent on barbiturates may be given phenobarbital 3 to 10 mg/kg/day. After withdrawal symptoms (hyperactivity, disturbed sleep, tremors, hyperreflexia) are relieved, the dosage of phenobarbital should be gradually decreased and completely withdrawn over a 2-week period.

OVERDOSAGE

The toxic dose of barbiturates varies considerably. In general, an oral dose of 1 gram of most barbiturates produces serious poisoning in an adult. Death commonly occurs after 2 to 10 grams of ingested barbiturate. Barbiturate intoxication may be confused with alcoholism, bromide intoxication, and with various neurological disorders.

Acute overdosage with barbiturates is manifested by CNS and respiratory depression which may progress to Cheyne-Stokes respiration, areflexia, constriction of the pupils to a slight degree (though in severe poisoning they may show paralytic dilation), oliguria, tachycardia, hypotension, lowered body temperature, and coma. Typical shock syndrome (apnea, circulatory collapse, respiratory arrest, and death) may occur. In extreme overdose, all electrical activity in the brain may cease, in which case a "flat" EEG normally equated with clinical death cannot be accepted. This effect is fully reversible unless hypoxic damage occurs. Consideration should be given to the possibility of barbiturate intoxication even in situations that appear to involve trauma.

Complications such as pneumonia, pulmonary edema, cardiac arrhythmias, congestive heart failure, and renal failure may occur. Uremia may increase CNS sensitivity to barbiturates. Differential diagnosis should include hypoglycemia, head trauma, cerebrovascular accidents, convulsive states, and diabetic coma.

Blood levels from acute overdosage for some barbiturates are listed in Table 1.

Table 1. Concentration of Barbiturate in the Blood Versus Degree of CNS Depression

Blood barbiturate level in ppm (µg/mL)

Barbiturate	Onset/ duration	Blood barbiturate level in ppm (µg/mL) Degree of depression in nontolerant persons* 1	2	3	4	5
Pentobarbital	Fast/short	≤2	0.5 to 3	10 to 15	12 to 25	15 to 40
Secobarbital	Fast/short	≤2	0.5 to 5	10 to 15	15 to 25	15 to 40
Amobarbital	Intermediate/ intermediate	≤3	2 to 10	30 to 40	30 to 60	40 to 80
Butabarbital	Intermediate/ intermediate	≤5	3 to 25	40 to 60	50 to 80	60 to 100
Phenobarbital	Slow/long	≤10	5 to 40	50 to 80	70 to 120	100 to 200

*Categories of degree of depression in nontolerant persons:

1. Under the influence and appreciably impaired for purposes of driving a motor vehicle or performing tasks requiring alertness and unimpaired judgment and reaction time.
2. Sedated, therapeutic range, calm, relaxed, and easily aroused.
3. Comatose, difficult to arouse, significant depression of respiration.
4. Compatible with death in aged or ill persons or in presence of obstructed airway, other toxic agents, or exposure to cold.
5. Usual lethal level, the upper end of the range includes those who received some supportive treatment.

Treatment of overdosage is mainly supportive and consists of the following:

1. Maintenance of an adequate airway, with assisted respiration and oxygen administration as necessary.
2. Monitoring of vital signs and fluid balance.
3. Fluid therapy and other standard treatment for shock, if needed.
4. If renal function is normal, forced diuresis may aid in the elimination of the barbiturate. Alkalinization of the urine increases renal excretion of some barbiturates, especially phenobarbital, also aprobarbital and mephobarbital (which is metabolized to phenobarbital).
5. Although not recommended as a routine procedure, hemodialysis may be used in severe barbiturate intoxications or if the patient is anuric or in shock.
6. Patient should be rolled from side to side every 30 minutes.
7. Antibiotics should be given if pneumonia is suspected.
8. Appropriate nursing care to prevent hypostatic pneumonia, decubiti, aspiration, and other complications of patients with altered states of consciousness.

DOSAGE AND ADMINISTRATION

Dosages of barbiturates must be individualized with full knowledge of their particular characteristics and recommended rate of administration. Factors of consideration are the patient's age, weight, and condition. Parenteral routes should be used only when oral administration is impossible or impractical.

Intramuscular Administration: IM injection of the sodium salts of barbiturates should be made deeply into a large muscle, and a volume of 5 mL should not be exceeded at any one site because of possible tissue irritation. After IM injection of a hypnotic dose, the patient's vital signs should be monitored. The usual adult dosage of NEMBUTAL Sodium Solution is 150 to 200 mg as a single IM injection; the recommended pediatric dosage ranges from 2 to 6 mg/kg as a single IM injection not to exceed 100 mg.

Intravenous Administration: NEMBUTAL Sodium Solution should not be admixed with any other medication or solution. IV injection is restricted to conditions in which other routes are not feasible, either because the patient is unconscious (as in cerebral hemorrhage, eclampsia, or status epilepticus), or because the patient resists (as in delirium), or because prompt action is imperative. Slow IV injection is essential, and patients should be carefully observed during administration. This requires that blood pressure, respiration, and cardiac function be maintained, vital signs be recorded, and equipment for resuscitation and artificial ventilation be available. The rate of IV injection should not exceed 50 mg/min for pentobarbital sodium.

There is no average intravenous dose of NEMBUTAL Sodium Solution (pentobarbital sodium injection) that can be relied on to produce similar effects in different patients. The possibility of overdose and respiratory depression is remote when the drug is injected slowly in fractional doses.

A commonly used initial dose for the 70 kg adult is 100 mg. Proportional reduction in dosage should be made for pediatric or debilitated patients. At least one minute is necessary to determine the full effect of

A commonly used initial dose for the 70 kg adult is 100 mg. Proportional reduction in dosage should be made for pediatric or debilitated patients. At least one minute is necessary to determine the full effect of intravenous pentobarbital. If necessary, additional small increments of the drug may be given up to a total of from 200 to 500 mg for normal adults.

Anticonvulsant use: In convulsive states, dosage of NEMBUTAL Sodium Solution should be kept to a minimum to avoid compounding the depression which may follow convulsions. The injection must be made slowly with due regard to the time required for the drug to penetrate the blood-brain barrier.

Special patient population: Dosage should be reduced in the elderly or debilitated because these patients may be more sensitive to barbiturates. Dosage should be reduced for patients with impaired renal function or hepatic disease.

Inspection: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution containers permit. Solutions for injection showing evidence of precipitation should not be used.

HOW SUPPLIED

NEMBUTAL Sodium Solution (pentobarbital sodium injection, USP) is available in the following sizes: 20-mL multiple-dose vial, 1 g per vial (NDC 67386-501-52); and 50-mL multiple-dose vial, 2.5 g per vial (NDC 67386-501-55).

Each mL contains:

Pentobarbital Sodium, derivative of barbituric acid	50 mg
Propylene glycol	40% v/v
Alcohol	10%
Water for Injection	qs

(pH adjusted to approximately 9.5 with hydrochloric acid and/or sodium hydroxide.)
Vial stoppers are latex free.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at 20-25°C (68-77°F); however, brief excursions are permitted between 15-30°C (59-86°F). See USP controlled room temperature.

[redacted]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Edward Harold Schad, Jr., Plaintiff, v. Janice K. Brewer, et al., Defendants.	Case No.2:13-cv-02001-ROS **Order**

Robert Glen Jones, Jr., has moved to intervene in this matter pursuant to Fed. R. Civ. P. 24. Upon consideration of the motion, Robert Glen Jones's Motion to Intervene is granted.

IT IS SO ORDERED.